



7-6-04

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PHA 4230.6  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Ellen G. McMahon, et al. Art Unit 1614  
Serial No. 10/803,317  
Filed March 18, 2004  
Confirmation No. 5758  
For COMBINATION OF AN ALDOSTERONE RECEPTOR ANTAGONIST AND A  
NEUTRAL ENDOPEPTIDASE INHIBITOR

July 2, 2004

COMMISSIONER FOR PATENTS  
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SIR:

INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R.

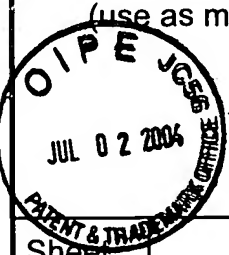
- \* 1.56, applicants submit the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the OG notice of August 5, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S.
- \* patent documents are not supplied. Applicants submit herewith copies of the foreign patent documents/literature references.

Respectfully submitted,

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ARK/crm/leb  
\*Enclosures

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<b>PTO/SB/08A</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)  		<b>Complete if Known</b>	
		Application Number	10/803,317
		Filing Date	March 18, 2004
		Confirmation Number	5758
		First Named Inventor	McMahon, et al.
		Group Art Unit	1614
		Examiner Name	To Be Assigned
Sheet 1 of 4	Attorney Docket No.	PHA 4230.6	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	1	4,046,889		Ondetti, et al.	09-06-1977
	2	4,105,776		Ondetti, et al.	08-08-1978
	3	4,337,201		Petrillo, Jr.	06-29-1982
	4	4,344,949		Hoefle, et al.	08-17-1982
	5	4,374,829		Harris, et al.	02-22-1983
	6	4,410,520		Watthey	10-18-1983
	7	4,508,729		Vincent, et al.	04-02-1985
	8	4,555,502		Patchett, et al.	11-26-1985
	9	4,559,332		Grob, et al.	12-17-1985
	10	4,587,258		Gold, et al.	05-06-1986
	11	4,933,361		Urbach, et al.	06-12-1990
	12	5,192,800		Barnish, et al.	03-09-1993
	13	5,508,272		Robl	04-16-1996
	14	5,618,970		Challenger	04-08-1997
	15	5,952,327		Waldeck, et al.	09-14-1999

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

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FOREIGN PATENT DOCUMENTS							
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		Office	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)			
	16	EP	0094095	B1	Attwood, et al.	11-05-1983	
	17	EP	0358398	B1	Danilewicz, et al.	03-14-1990	
	18	EP	0599444	A1	Karanewsky, et al.	06-01-1994	
	19	EP	0629627	A2	Robl, et al.	12-21-1994	
	20	WO	00/27380	A2	Perez, et al.	05-18-2000	
	21	WO	00/51642	A1	Alexander, et al.	09-08-2000	
	22	WO	01/87284	A2	Garthwaite, et al.	11-22-2001	
	23	WO	01/95892	A1	Williams, et al.	12-20-2001	
	24	WO	01/95893	A1	Williams, et al.	12-20-2001	
	25	WO	02/09683	A2	Rocha, et al.	02-07-2002	
	26	WO	02/09759	A2	Rocha, et al.	02-07-2002	
	27	WO	02/09760	A2	Alexander, et al.	02-07-2002	
	28	WO	02/09761	A2	Schuh	02-07-2002	
	29	WO	95/15308	A1	Dunn, et al.	06-08-1995	
	30	WO	96/40255	A2	Egan, et al.	12-19-1996	
	31	WO	96/40257	A1	Alexander, et al.	12-19-1996	

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OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	32	Bertram Pitt, M.D., et al., The Effect of Spironolactone on Morbidity and Mortality in Patients with Severe Heart Failure, The New England Journal of Medicine, September 2, 1999, pgs. 709-717, Vol. 341 No. 10	
	33	Henry Krum, New and Emerging Pharmacologic Strategies in the Management of Chronic Heart Failure, Clin. Cardiol., 2000, pgs. 724-730, Vol. 23	
	34	J. Bralet, et al., Fasidotril: The First Dual Inhibitor of Neprilysin and ACE, Cardiovascular Drug Reviews, 2000, Vol. 18, No. 1	
	35	Mojgan Sani, Vasoepitidase Inhibitors: An Emerging Class of Cardiovascular Drugs, Hospital Pharmacist, November/December 2001, pgs. 280-282, Vol. 8	
	36	Jean Bralet, et al., Vasoepitidase Inhibitors: An Emerging Class of Cardiovascular Drugs, Trends in Pharmacological Sciences, March 2001, pgs. 106-109, Vol. 22, No. 3	
	37	Toshiyuki Maki, et al., Long-Term Treatment with Neutral Endopeptidase Inhibitor Improves Cardiac Function and Reduces Natriuretic Peptides in Rats with Chronic Heart Failure, Cardiovascular Research, 2001, pgs. 608-617, Vol. 51	
	38	Toru Suzuki, et al., The Role of the Natriuretic Peptides in the Cardiovascular System, Cardiovascular Research, 2001, pgs. 489-494, Vol. 51	
	39	Amy E. Rudolph, et al., Emerging Therapies for Heart Failure, Expert Opin. Emerging Drugs, 2002, pgs. 247-258, Vol. 7(2)	
	40	Bristol-Myers Squibb Pharmaceutical Research Institute, Bristol Myers Squibb Company, FDA Advisory Committee Briefing Book for Omapatrilat Tablets NDA 21-188, pgs. 1-154, July 2002	
	41	Hans Peter Brunner-La Rocca, et al., Therapeutic Benefits of Increasing Natriuretic Peptide Levels, Cardiovascular Research, 2001, pgs. 510-520, Vol. 51	

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	42	Giuseppe A. Sagnella, Atrial Natriuretic Peptide Mimetics and Vasopeptidase Inhibitors, Cardiovascular Research, 2001, pgs. 416-428, Vol. 51	
	43	Surakit Nathisuwan, et al., A Review of Vasopeptidase Inhibitors: A New Modality in the Treatment of Hypertension and Chronic Heart Failure, Pharmacotherapy, 2002, pgs. 27-42, Vol. 22(1)	

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